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Gary Karlin Michelson M D

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EXAMINER

SEVERSON, RYAN J

ART UNIT

PAPER NUMBER

3731

MAIL DATE

DELIVERY MODE

10/01/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 09/626,636	Applicant(s) MICHELSON M D, GARY KARLIN	
	Examiner Ryan J. Severson	Art Unit 3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 August 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 172-176, 178-208, 210-212, 215-256, 258-276, 278-318 and 320-350 is/are pending in the application.
- 4a) Of the above claim(s) 185-189, 196, 200, 203-206, 227-236 and 239-246 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) See Continuation Sheet is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>8/5/2009</u> . | 6) <input type="checkbox"/> Other: _____ |

Continuation of Disposition of Claims: Claims rejected are 172-176,178-184,190-195,201,202,207,208,210-212,215-226,237,238,247-256,258-276,278-318 and 320-350.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114 was filed in this application after appeal to the Board of Patent Appeals and Interferences, but prior to a decision on the appeal. Since this application is eligible for continued examination under 37 CFR 1.114 and the fee set forth in 37 CFR 1.17(e) has been timely paid, the appeal has been withdrawn pursuant to 37 CFR 1.114 and prosecution in this application has been reopened pursuant to 37 CFR 1.114. Applicant's submission filed on 8/5/2009 has been entered.

Response to Amendment

2. Examiner notes that applicant has not filed any new arguments or amendments in conjunction with the RCE. Therefore, all previous responses to arguments (as set forth in the final rejection of 8/6/2008 and in the advisory action of 11/26/2008) are incorporated herein and repeated below in the "Response to Arguments" section.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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4. **Claims 172-176, 178-184, 201, 202, 247, 331, and 344-346 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brantigan (4,878,915) in view of Laurain (5,108,395) and Cozad (5,049,150).** Brantigan discloses the apparatus substantially as claimed including a guard (22, see figure 4) having engaging portions (23) at the distal end thereof that are capable of engaging and penetrating adjacent vertebral bodies. The guard is a hollow sleeve that is circular in cross-section. Also included in the Brantigan disclosure is a bone removal device (21), an implant (11) and an implant driver (25, see figure 5). The bone removal device also can act as a distractor because it engages adjacent vertebral bodies substantially as claimed. The engaging portions are tapered and have flat portions there between to prevent over-insertion of the engaging portions into the adjacent vertebral bodies. The distal end of the bone boring device caps the proximal end of the guard and provides a depth limiting shoulder to prevent over-insertion of either the bone removal device or the implant driver (as shown in figures 4 and 5).
5. Regarding claim 172, Brantigan reference does not disclose the distal end of the guard has a concave curve. Attention is drawn to Laurain reference, which discloses it is known to have the engagement end of a spinal device formed with a concave curvature (see figure 3B) to allow for more complete engagement of the device with the spine. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have the distal end of the guard of Brantigan formed with a concave surface, as taught by Laurain reference, to allow for more complete engagement of the guard to the vertebral bodies.

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6. Further regarding claim 172, the combination of Brantigan and Laurain references does not disclose the engaging portions are inline with the sides of the guard. Attention is drawn to Cozad reference, which teaches it is known to have a guard with a constant outer diameter to minimize the diameter of the device thereby providing a less invasive device. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have the distal end of the guard of the combination of Brantigan and Laurain references shaped as taught by Cozad reference to minimize the diameter of the device.

7. Regarding claim 176, the guard (22) of Brantigan does not disclose an increased diameter portion at its proximal end. Attention is drawn to figure 5 of Brantigan, which shows another sleeve or guard with an increased diameter portion at the proximal end to facilitate easier handling of the guard by the surgeon. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to include the increased diameter portion of figure 5 on the guard shown in figure 4 to facilitate easier handling of the guard by the surgeon.

8. **Claims 207, 208, 210-212, 215-218, 220-226, 237, and 238 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brantigan (4,878,915) in view of Cozad (5,049,150) and Morrison (3,486,505).** Brantigan discloses the apparatus substantially as claimed including a guard (22, see figure 4) having engaging portions (23) at the distal end thereof that are capable of engaging and penetrating adjacent vertebral bodies. The guard is a hollow sleeve that is circular in cross-section. Also included in the Brantigan disclosure is a bone removal device (21), an implant (11) and

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an implant driver (25, see figure 5). The bone removal device also can act as a distractor because it engages adjacent vertebral bodies substantially as claimed. The engaging portions are tapered and have flat portions there between to prevent over-insertion of the engaging portions into the adjacent vertebral bodies. The distal end of the bone boring device caps the proximal end of the guard and provides a depth limiting shoulder to prevent over-insertion of either the bone removal device or the implant driver (as shown in figures 4 and 5).

9. Regarding claim 207, Brantigan reference does not disclose the engaging portions are inline with the sides of the guard. Attention is drawn to Cozad reference, which teaches it is known to have a guard with a constant outer diameter to minimize the diameter of the device thereby providing a less invasive device. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have the distal end of the guard of Brantigan reference shaped as taught by Cozad reference to minimize the diameter of the device.

10. Further regarding claim 207, the combination of Brantigan and Cozad references does not disclose slots in the side walls of the guard. Attention is drawn to Morrison reference, which teaches the use of slots (13) in a guard to allow the distal ends of the guard to spread to deploy an implant but also to maintain a minimal size of the distal end of the device when the implant is not being deployed. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to include slots with the guard of the combination of Brantigan and Cozad references, as taught by Morrison reference, to allow the distal ends of the guard to spread to deploy

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an implant but also to maintain a minimal size of the distal end of the device when the implant is not being deployed.

11. Regarding claim 218, the guard with slots as set forth above in the non-expanded shape would have a larger proximal end (as illustrated in Figure 2 of Morrison).

12. **Claims 248-256, 258-269, 276, 278-286, and 347-349 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brantigan (4,878,915) in view of Laurain (5,108,395) and Cozad (5,049,150).** Brantigan discloses the apparatus substantially as claimed including a guard (22, see figure 4) having extensions (23) at the distal end thereof that are capable of engaging and penetrating adjacent vertebral bodies. The guard is a hollow sleeve that is circular in cross-section. Also included in the Brantigan disclosure is a bone removal device (21), an implant (11) and an implant driver (25, see figure 5). The bone removal device also can act as a distractor because it engages adjacent vertebral bodies substantially as claimed. The extensions are tapered and have flat portions there between to prevent over-insertion of the engaging portions into the adjacent vertebral bodies. The distal end of the bone boring device caps the proximal end of the guard and provides a depth limiting shoulder to prevent over-insertion of either the bone removal device or the implant driver (as shown in figures 4 and 5). An inner guard (the portion of the bone drill that the drill bit 21 is screwed into) is slidably received in the guard (see figure 4).

13. Regarding claim 248, Brantigan reference does not disclose the distal end of the guard has a concave curve. Attention is drawn to Laurain reference, which discloses it is known to have the engagement end of a spinal device formed with a concave

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curvature (see figure 3B) to allow for more complete engagement of the device with the spine. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have the distal end of the guard of Brantigan formed with a concave surface, as taught by Laurain reference, to allow for more complete engagement of the guard to the vertebral bodies.

14. Further regarding claim 248, the combination of Brantigan and Laurain references does not disclose the extensions are inline with the sides of the guard. Attention is drawn to Cozad reference, which teaches it is known to have a guard with a constant outer diameter to minimize the diameter of the device thereby providing a less invasive device. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have the distal end of the guard of the combination of Brantigan and Laurain references shaped as taught by Cozad reference to minimize the diameter of the device.

15. Also regarding claims 248 and 249, the combination of Brantigan, Laurain, and Cozad references does not disclose the specific size of the passage of the guard. However, it has been held that where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges." *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).

16. Regarding claim 256, the guard (22) of Brantigan does not disclose an increased diameter portion at its proximal end. Attention is drawn to figure 5 of Brantigan, which shows another sleeve or guard with an increased diameter portion at the proximal end to facilitate easier handling of the guard by the surgeon. Therefore, it would have been

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obvious to one of ordinary skill in the art at the time the invention was made to include the increased diameter portion of figure 5 on the guard shown in figure 4 to facilitate easier handling of the guard by the surgeon.

17. **Claims 289-304, 306-318, and 320-329 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brantigan (4,878,915) in view of Cozad (5,049,150) and Codman (Ruptured Cervical Intervertebral Discs article).** Brantigan discloses the apparatus substantially as claimed including a guard (22, see figure 4) having extensions (23) at the distal end thereof that are capable of engaging and penetrating adjacent vertebral bodies. The guard is a hollow sleeve that is circular in cross-section. Also included in the Brantigan disclosure is a bone removal device (21), an implant (11) and an implant driver (25, see figure 5). The bone removal device also can act as a distractor because it engages adjacent vertebral bodies substantially as claimed. The extensions are tapered and have flat portions there between to prevent over-insertion of the engaging portions into the adjacent vertebral bodies. The distal end of the bone boring device caps the proximal end of the guard and provides a depth limiting shoulder to prevent over-insertion of either the bone removal device or the implant driver (as shown in figures 4 and 5). An inner guard (the portion of the bone drill that the drill bit 21 is screwed into) is slidably received in the guard (see figure 4).

18. Regarding claim 289, Brantigan reference does not disclose the engaging portions are inline with the sides of the guard. Attention is drawn to Cozad reference, which teaches it is know to have a guard with a constant outer diameter to minimize the diameter of the device thereby providing a less invasive device. Therefore, it would

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have been obvious to one of ordinary skill in the art at the time the invention was made to have the distal end of the guard of Brantigan reference shaped as taught by Cozad reference to minimize the diameter of the device.

19. Further regarding claim 289, the combination of Brantigan and Cozad references does not disclose openings in the side walls of the guard. Attention is drawn to Codman reference, which teaches the use of an opening (see figures 23 and 24) that is used to allow drill dust to escape from the guard thereby preventing the drill from binding.

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to include the opening of Codman with the guard of the combination of Brantigan and Cozad references to prevent the drill (as in figure 4 of Brantigan) from binding.

20. Further regarding claim 289, the combination of Brantigan, Cozad, and Codman references do not disclose more than one opening in the guard. However, it has been held that mere duplication of parts has no patentable significance unless a new and unexpected result is produced. *In re Harza*, 274 F.2d 669, 124 USPQ 378 (CCPA 1960). Therefore, since having an additional opening would produce no new and unexpected result, one of ordinary skill in the art at the time the invention was made would have recognized that having a plurality of openings would have been obvious in view of the teaching of Codman reference.

21. Also regarding claims 289 and 290, the combination of Brantigan, Cozad, and Codman references does not disclose the specific size of the passage of the guard. However, it has been held that where the general conditions of a claim are disclosed in

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the prior art, it is not inventive to discover the optimum or workable ranges.” *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).

22. Regarding claim 304, the guard (22) of Brantigan does not disclose an increased diameter portion at its proximal end. Attention is drawn to figure 5 of Brantigan, which shows another sleeve or guard with an increased diameter portion at the proximal end to facilitate easier handling of the guard by the surgeon. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to include the increased diameter portion of figure 5 on the guard shown in figure 4 to facilitate easier handling of the guard by the surgeon.

23. **Claims 332, 335-337, 339, and 341-343 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brantigan (4,878,915) in view of Cozad (5,049,150).**

Brantigan discloses the apparatus substantially as claimed including a guard (22, see figure 4) having extensions (23) at the distal end thereof that are capable of engaging and penetrating adjacent vertebral bodies. The guard is a hollow sleeve that is circular in cross-section. Also included in the Brantigan disclosure is a bone removal device (21), an implant (11) and an implant driver (25, see figure 5). The bone removal device also can act as a distractor because it engages adjacent vertebral bodies substantially as claimed. The extensions are tapered and have flat portions there between to prevent over-insertion of the engaging portions into the adjacent vertebral bodies. The distal end of the bone boring device caps the proximal end of the guard and provides a depth limiting shoulder to prevent over-insertion of either the bone removal device or the implant driver (as shown in figures 4 and 5).

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24. Regarding claim 332, Brantigan reference does not disclose the engaging portions are inline with the sides of the guard. Attention is drawn to Cozad reference, which teaches it is known to have a guard with a constant outer diameter to minimize the diameter of the device thereby providing a less invasive device. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have the distal end of the guard of Brantigan reference shaped as taught by Cozad reference to minimize the diameter of the device.

25. Also regarding claims 332 and 335, the combination of Brantigan and Cozad references does not disclose the specific size of the passage of the guard. However, it has been held that where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges." *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).

26. **Claim 350 is rejected under 35 U.S.C. 103(a) as being unpatentable over Brantigan (4,878,915) in view of Laurain (5,108,395), Cozad (5,049,150), and Codman (Ruptured Cervical Intervertebral Discs article).** Brantigan discloses the apparatus substantially as claimed including a guard (22, see figure 4) having engaging portions (23) at the distal end thereof that are capable of engaging and penetrating adjacent vertebral bodies. The guard is a hollow sleeve that is circular in cross-section. Also included in the Brantigan disclosure is a bone removal device (21), an implant (11) and an implant driver (25, see figure 5). The bone removal device also can act as a distractor because it engages adjacent vertebral bodies substantially as claimed. The engaging portions are tapered and have flat portions there between to prevent over-

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insertion of the engaging portions into the adjacent vertebral bodies. The distal end of the bone boring device caps the proximal end of the guard and provides a depth limiting shoulder to prevent over-insertion of either the bone removal device or the implant driver (as shown in figures 4 and 5).

27. Regarding claim 350, Brantigan reference does not disclose the distal end of the guard has a concave curve. Attention is drawn to Laurain reference, which discloses it is known to have the engagement end of a spinal device formed with a concave curvature (see figure 3B) to allow for more complete engagement of the device with the spine. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have the distal end of the guard of Brantigan formed with a concave surface, as taught by Laurain reference, to allow for more complete engagement of the guard to the vertebral bodies.

28. Further regarding claim 350, the combination of Brantigan and Laurain references does not disclose the engaging portions are inline with the sides of the guard. Attention is drawn to Cozad reference, which teaches it is known to have a guard with a constant outer diameter to minimize the diameter of the device thereby providing a less invasive device. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have the distal end of the guard of the combination of Brantigan and Laurain references shaped as taught by Cozad reference to minimize the diameter of the device.

29. Further regarding claim 350, the combination of Brantigan, Laurain, and Cozad does not disclose openings in the side walls of the guard. Attention is drawn to Codman

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reference, which teaches the use of an opening (see figures 23 and 24) that is used to allow drill dust to escape from the guard thereby preventing the drill from binding.

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to include the opening of Codman with the guard of the combination of Brantigan, Laurain, and Cozad references to prevent the drill (as in figure 4 of Brantigan) from binding.

30. Further regarding claim 350, the combination of Brantigan, Laurain, Cozad, and Codman references do not disclose more than one opening in the guard. However, it has been held that mere duplication of parts has no patentable significance unless a new and unexpected result is produced. *In re Harza*, 274 F.2d 669, 124 USPQ 378 (CCPA 1960). Therefore, since having an additional opening would produce no new and unexpected result, one of ordinary skill in the art at the time the invention was made would have recognized that having a plurality of openings would have been obvious in view of the teaching of Codman reference.

31. **Claims 190-195 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brantigan (4,878,915) in view of Laurain (5,108,395) and Cozad (5,049,150) as applied to claim 172 above, and further in view of Codman (Ruptured Cervical Intervertebral Discs article).** The combination of Brantigan, Laurain, and Cozad does not disclose openings in the side walls of the guard. Attention is drawn to Codman reference, which teaches the use of an opening (see figures 23 and 24) that is used to allow drill dust to escape from the guard thereby preventing the drill from binding.

Therefore, it would have been obvious to one of ordinary skill in the art at the time the

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invention was made to include the opening of Codman with the guard of the combination of Brantigan, Laurain, and Cozad references to prevent the drill (as in figure 4 of Brantigan) from binding.

32. Further regarding claims 190-195, the combination of Brantigan, Laurain, Cozad, and Codman references do not disclose more than one opening in the guard. However, it has been held that mere duplication of parts has no patentable significance unless a new and unexpected result is produced. *In re Harza*, 274 F.2d 669, 124 USPQ 378 (CCPA 1960). Therefore, since having an additional opening would produce no new and unexpected result, one of ordinary skill in the art at the time the invention was made would have recognized that having a plurality of openings would have been obvious in view of the teaching of Codman reference.

33. **Claim 219 is rejected under 35 U.S.C. 103(a) as being unpatentable over Brantigan (4,878,915) in view of Cozad (5,049,150) and Morrison (3,486,505) as applied to claim 207 above, and further in view of Laurain (5,108,395).** The combination of Brantigan, Cozad, and Morrison does not disclose a concave curved distal end of the guard. Attention is drawn to Laurain reference, which discloses it is known to have the engagement end of a spinal device formed with a concave curvature (see figure 3B) to allow for more complete engagement of the device with the spine. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have the distal end of the guard of the combination of Brantigan, Cozad, and Morrison references formed with a concave surface, as taught by Laurain reference, to allow for more complete engagement of the guard to the vertebral bodies.

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34. **Claims 270-275 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brantigan (4,878,915) in view of Laurain (5,108,395) and Cozad (5,049,150) as applied to claim 248 above, and further in view of Codman (Ruptured Cervical Intervertebral Discs article).** The combination of Brantigan, Laurain, and Cozad does not disclose openings in the side walls of the guard. Attention is drawn to Codman reference, which teaches the use of an opening (see figures 23 and 24) that is used to allow drill dust to escape from the guard thereby preventing the drill from binding. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to include the opening of Codman with the guard of the combination of Brantigan, Laurain, and Cozad references to prevent the drill (as in figure 4 of Brantigan) from binding.

35. Further regarding claims 270-275, the combination of Brantigan, Laurain, Cozad, and Codman references do not disclose more than one opening in the guard. However, it has been held that mere duplication of parts has no patentable significance unless a new and unexpected result is produced. *In re Harza*, 274 F.2d 669, 124 USPQ 378 (CCPA 1960). Therefore, since having an additional opening would produce no new and unexpected result, one of ordinary skill in the art at the time the invention was made would have recognized that having a plurality of openings would have been obvious in view of the teaching of Codman reference.

36. **Claims 287 and 288 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brantigan (4,878,915) in view of Laurain (5,108,395) and Cozad (5,049,150) as applied to claim 286 above, and further in view of Mathews**

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(5,357,983). The combination of Brantigan, Laurain, and Cozad does not disclose the implant being harvested bone to promote fusion. Attention is drawn to Mathews reference, which teaches it is well-known in the art to have a spinal implant made of harvested bone to promote fusion between the implant and the adjacent body tissues (see column 7, lines 1-2). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to make the implant of the combination of Brantigan, Laurain, and Cozad references of harvested bone, as taught by Mathews reference, promote fusion between the implant and the adjacent body tissues.

37. Claim 305 is rejected under 35 U.S.C. 103(a) as being unpatentable over Brantigan (4,878,915) in view of Cozad (5,049,150) and Codman (Ruptured Cervical Intervertebral Discs article) as applied to claim 289 above, and further in view of Laurain (5,108,395). The combination of Brantigan, Cozad, and Codman does not disclose a concave curved distal end of the guard. Attention is drawn to Laurain reference, which discloses it is known to have the engagement end of a spinal device formed with a concave curvature (see figure 3B) to allow for more complete engagement of the device with the spine. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have the distal end of the guard of the combination of Brantigan, Cozad, and Codman references formed with a concave surface, as taught by Laurain reference, to allow for more complete engagement of the guard to the vertebral bodies.

38. Claims 329 and 330 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brantigan (4,878,915) in view of Cozad (5,049,150) and Codman

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(Ruptured Cervical Intervertebral Discs article) as applied to claim 328 above, and

further in view of Mathews (5,357,983). The combination of Brantigan, Cozad, and

Codman does not disclose the implant being harvested bone to promote fusion.

Attention is drawn to Mathews reference, which teaches it is well-known in the art to have a spinal implant made of harvested bone to promote fusion between the implant and the adjacent body tissues (see column 7, lines 1-2). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to make the implant of the combination of Brantigan, Cozad, and Codman references of harvested bone, as taught by Mathews reference, promote fusion between the implant and the adjacent body tissues.

39. **Claims 333 and 334 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brantigan (4,878,915) in view of Cozad (5,049,150) as applied to claim 332 above, and further in view of Mathews (5,357,983).** The combination of Brantigan and Cozad does not disclose the implant being harvested bone to promote fusion. Attention is drawn to Mathews reference, which teaches it is well-known in the art to have a spinal implant made of harvested bone to promote fusion between the implant and the adjacent body tissues (see column 7, lines 1-2). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to make the implant of the combination of Brantigan and Cozad references of harvested bone, as taught by Mathews reference, promote fusion between the implant and the adjacent body tissues.

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40. **Claim 338 is rejected under 35 U.S.C. 103(a) as being unpatentable over Brantigan (4,878,915) in view of Cozad (5,049,150) as applied to claim 332 above, and further in view of Laurain (5,108,395).** The combination of Brantigan and Cozad does not disclose a concave curved distal end of the guard. Attention is drawn to Laurain reference, which discloses it is known to have the engagement end of a spinal device formed with a concave curvature (see figure 3B) to allow for more complete engagement of the device with the spine. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have the distal end of the guard of the combination of Brantigan and Cozad references formed with a concave surface, as taught by Laurain reference, to allow for more complete engagement of the guard to the vertebral bodies.

41. **Claim 340 is rejected under 35 U.S.C. 103(a) as being unpatentable over Brantigan (4,878,915) in view of Cozad (5,049,150) as applied to claim 332 above, and further in view of Codman (Ruptured Cervical Intervertebral Discs article).** The combination of Brantigan and Cozad does not disclose openings in the side walls of the guard. Attention is drawn to Codman reference, which teaches the use of an opening (see figures 23 and 24) that is used to allow drill dust to escape from the guard thereby preventing the drill from binding. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to include the opening of Codman with the guard of the combination of Brantigan and Cozad references to prevent the drill (as in figure 4 of Brantigan) from binding.

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42. Further regarding claim 340, the combination of Brantigan, Cozad, and Codman references do not disclose more than one opening in the guard. However, it has been held that mere duplication of parts has no patentable significance unless a new and unexpected result is produced. *In re Harza*, 274 F.2d 669, 124 USPQ 378 (CCPA 1960). Therefore, since having an additional opening would produce no new and unexpected result, one of ordinary skill in the art at the time the invention was made would have recognized that having a plurality of openings would have been obvious in view of the teaching of Codman reference.

Response to Arguments

43. Applicant argues with respect to claim 289 that Brantigan does not have an implant and implant driver. However, as described above, Brantigan does disclose these features, and therefore the argument is not persuasive. Applicant argues with respect to claim 332 that Brantigan does not have a hole in the wall. However, the distal opening in the wall can be considered the hole or opening as required by the claim, and therefore the argument is not persuasive.

44. Applicant argues the curve of Laurain does not meet the limitation requiring the center of the curve to be located more proximal than the ends. However, applicant appears to have merely ignored part of the structure of Laurain and also ignored the combination proposed. The center of the concave curve of Laurain not the center of the tubular portion (12) upon which applicant bases this argument. Examiner has merely used the generally curved, contour shape of Laurain as a teaching for making the end of

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the Brantigan device concavely curved. Doing so would provide a structure that meets the structural limitations of the claims. Therefore, this argument is not persuasive.

45. Applicant argues both Brantigan and Cozad teach away from Laurain because Brantigan and Cozad have devices where the ends terminate in a perpendicular plane and Laurain has an end that contours to the bone. However, this is the reason the combination is made (to allow the device of Brantigan and Cozad to contour to bone). Therefore, it is unclear how the references teach away from one another. Laurain provides an feature that is desirable, and adding that feature to Brantigan in no way is teaching away from the functionality or structure of Brantigan. Therefore, this argument is not persuasive.

46. Applicant argues both Brantigan and Cozad teach away from Morrison because Brantigan and Cozad are tubular and Morrison is not. However, Examiner has only relied on the notion of including slots in the side of the devices of Brantigan and Cozad, and not modifying the fact that those devices are generally tubular in shape. With slots included in the Brantigan device, the device would still be generally tubular in shape, with each half of the tube separated by the slots. Therefore, this argument is not persuasive.

47. Applicant argues the combination of Brantigan, Cozad, and Codman does not disclose a hollow guard, an implant, and an implant driver. Examiner directs applicants attention to paragraphs 15-20 of the outstanding final rejection, in which all of the structural limitations of the claims are set forth as being disclosed and/or obvious in view of the cited prior art. Therefore, this argument is not persuasive.

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48. Applicant argues the combination of Brantigan and Cozad does not disclose a wall that is continuous around the mid-longitudinal axis of the guard and an opening through the wall. However, Brantigan clearly discloses a solid wall (see, for example, figure 4) and an opening in the wall (the distal opening, for example). Therefore, this argument is not persuasive.

Conclusion

49. All claims are drawn to the same invention claimed in the application prior to the entry of the submission under 37 CFR 1.114 and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the application prior to entry under 37 CFR 1.114. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action after the filing of a request for continued examination and the submission under 37 CFR 1.114. See MPEP § 706.07(b).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

50. A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

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51. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ryan J. Severson whose telephone number is (571) 272-3142. The examiner can normally be reached on Monday - Friday 8:30-5:00.

52. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan Nguyen can be reached on (571) 272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

53. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/R. J. S./
Examiner, Art Unit 3731
9/29/09

/Anhtuan T. Nguyen/
Supervisory Patent Examiner, Art Unit 3731